Categorization of the Canadian Domestic Substances List

What is the Domestic Substances List (DSL)?

The Domestic Substances List (DSL) is a list of existing substances that are "in commerce" in Canada. Originally it contained approximately 23 000 substances. They may be grouped into discrete organics (50% of the substances listed), Unknown, Variable in composition, Complex reaction products, and Biologicals (UVCB's) (20%), polymers (20%) and inorganics (10%).

Why do we have a DSL List?

The DSL was created in 1991 for the purpose of defining a "new substance". A substance being nominated for the DSL would have to have been in use between 1984 and 1986 in Canadian commerce or used for commercial manufacturing in Canada, or manufactured or imported in Canada at >100 kg/year. Note that this list does not include contaminants, by-products and/or wastes.

What is Categorization of the DSL?

Mandated under CEPA 1999 (S.73) Ministers were required to categorize the 23,000 substances on the DSL by September 14, 2006 as a means of prioritization that involved the systematic identification of substances that should be subject to screening assessment (Section 74, CEPA 1999). This process was designed to be scientifically sound but practical and to allow sufficient and efficient stakeholder input.

The idea, simply, was to identify substances that may present the greatest potential for exposure to individuals in Canada; or are persistent (P) **or** bioaccumulative (B), in accordance with the Persistence and Bioaccumulation regulations, **and** inherently toxic to humans or to non-human organisms, as determined by lab or other studies.

What was the approach to Categorization?

Of considerable concern related to exposure to humans are substances identified as bioaccumulative or persistent. These substances are considered a subsection of the 23,000 substances listed and are identified as inherently toxic to humans.

The resulting Draft Maximal List was then released in October 2004. This list consisted of 1896 substances that required focused submission of information to fill in gaps in data. The Draft Maximal List itself was further revised based on consideration of new and submitted information, identification of those substances already assessed and/or managed under CEPA and the application of the Complex Hazard Tools to the moderate group of substances. The complex tools included the **Complex Exposure Tool (ComET)** which provided a quantitative estimate of upper bounding environmental and consumer exposure for multiple age groups based on use scenarios, and the **Complex Hazard Tool (ComHaz)** providing for a hierarchy of multiple toxicological endpoints and data sources - including QSAR. The endpoint of this analysis and application of tools was the Human Health Categorization Results.

Human Health Categorization Approach and Results

In order to properly prioritize these substances a number of tools, both simple and complex, were used. The simple tools included a **Simple Exposure Tool (SimET) -** for the relative ranking of all DSL substances based on submitters (S), quantity (Q) and expert ranked use (ERU) and the **Simple Hazard Tool (SimHaz)** which identified compounds as being high or low hazard as identified by various international agencies (ie IARC). SimET classified substances into three groups. These included Greatest Potential for Exposure (GPE), Intermediate Potential for Exposure (IPE) and Lowest Potential for Exposure (LPE).

The Human Health Categorization housed three groups. The first group was the **High Hazard Substances** consisting of High or Intermediate Exposure (~100) and Low Exposure (~160) substances. This group of substances was defined as having a high likelihood of human exposure and a high hazard to human health (e.g. carcinogenicity, developmental toxicant). The second group was the **Petroleum Stream Substances** consisting of substances with High Hazard and High/Intermediate Exposure (~160) and Low Exposure (~100) substances but that may be relevant mainly to the petroleum sector. Finally, the third group was the **High Exposure Substances** – substances with high or intermediate potential for exposure and identified as persistent or bioaccumulative from the ecological categorization(~680). This group of substances was identified as having a high likelihood of human exposure and likely to persist or bioaccumulate in the body.

Ecological Categorization Approach and Results

The ecological categorization aimed to identify all the substances on the DSL that met either the bioaccumulation (B) and/or the persistence (P) criteria and met the inherent toxicity to non-human organisms (iT) criteria. The process for ecological categorization was a massive effort involving members from industry, ENGOs, academics, governments, modeling experts, research centres and an invitation to the public for comment. The process followed a continuum employing the following steps - defining the technical approach, collecting empirical data and generation of QSAR predictions, applying scientific evaluation of this data, releasing preliminary decisions, calling for voluntary submission of data by stakeholders[1], scientific evaluation of that data, and finally, issuance of final categorization results in September 2006.

Criteria for bioaccumulation: BAF $\geq$ 5000 or BCF $\geq$ 5000 or log Kow $\geq$ 5

Criteria for persistence: If its transformation half-life satisfies the criterion in any one environmental medium or if it is subject to long-range transport. Air: Half-life: $\geq$ 2 days (or LRT), Water: $\geq$ 6 months Sediment: $\geq$ 1 year Soil: $\geq$ 6 months

[1] An 18 month voluntary challenge to industrial stakeholders and interested parties to submit experimental study or other information that could help to refine categorization decisions. Approximately 20 larger data submissions were received for consideration and more than 400 individual studies addressing P, B or aquatic toxicity. Also received were approximately 20 submissions covering the human health aspects of categorization. Of these experimental studies, for which there were more than 11,500 organic substances examined, experimental aquatic toxicity data was found for 1200 substances (80% accepted), experimental P data was found for 1500 substances (50% accepted) and experimental B data was found for 440 substances (80% accepted).

Criteria for Non-Human Inherent toxicity: Acute aquatic toxicity of $LC(EC)_{50} \leq 1$mg/L, or a chronic aquatic toxicity of NOEC ≤ 0.1 mg/L

Data preferences for P B iT profiles were as follows:

- Higher – Experimental
- Medium – Analogue / Groupings / Scientific rationale
- Lower – Modelled (QSAR)

The final categorization results were broken down into two groups – those **Not Considered** P /B and eco iT and those **Considered** P/B and eco iT.

Ecological Categorization Results:

	Number of Substances in each Tier		
	Experimental Data	Combination of Experimental & Modelled Data or Read-Across Data	Modelled Data
PBiT	28	82	287
High Volume PiT or BiT	210	153	20
Medium Volume PiT or BiT	425	352	337
Low Volume PiT or BiT	386	356	342
Unknown Volume PiT or BiT			159

*High Volume>= 1000T; Medium Volume >=1T and <1000T; Low Volume <1T

For more information please visit:

- Chemical Substances Website: http://www.chemicalsubstances.gc.ca
- Health Canada Existing Substances Division Website: http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/index_e.html
- Environment Canada Existing Substances Division Website: http://www.ec.gc.ca/substances/ese